REMARKS

Claims 17-23 are pending. Reconsideration is requested.

Claims 17-23 have been rejected under 35 USC § 103 as being obvious over Barsig (US PUB 2003/0092706) in view of Hellberg et al. (U.S. 6,452,052). This rejection is traversed for the following reasons.

The present claims relate to the treatment of respiratory diseases, allergic diseases, asthma and COPD with the special combination of loteprednol and DFHO. In contrast, Barsig refers to the combination of PDE4 inhibitors and disease-modifying antirheumatic drugs (DMARDs), especially for the treatment of rheumatoid arthritis. Barsig discloses DFHO as PDE4 inhibitor, and airway disorders of various origin as a potential further indication to be treated with the combination. However, the experimental data in this application are focused solely on the treatment of rheumatoid arthritis, analyzed using a model of collagen-induced arthritis in mice. The document does not demonstrate any special effect of PDE4 inhibitors and DMARDs in the treatment of any respiratory disease. The Examiner has acknowledged that loteprednol is not mentioned in this document.

The secondary reference, Hellberg et al., cites the potential use of loteprednol for the treatment of allergic diseases, but only in combination with the aniline disulfide derivatives, which are the focus of the invention in this document (mentioned there in the abstract or background of the invention). Loteprednol is only mentioned in a general listing amongst other substances of the groups of antihistamines, anti-inflammatory agents or decongestants. There is no special effect disclosed or suggested for the presently claimed combination, nor is any experimental data for such combination provided.

As already mentioned, the synergistic effect of the presently claimed combination is clearly demonstrated in the experimental data of the present application, which analyzes totally different parameters than the specific arthritis models of the prior art document. The experimental data in the present application show the synergistic reduction of granulocyte-macrophage colony stimulating factor (GM-CSF) or tumor necrosis factor (TNF) release from stimulated monocytes as an indicator for the reduction of inflammation. These molecules are important modulators of the inflammatory component of respiratory diseases such as asthma, COPD or allergic respiratory diseases. Thus, the synergistic effect has been shown using two different models. Both clearly

show the improved effect of the combination of loteprednol/DFHO in contrast to the single substances.

An additional aspect that must be considered is that loteprednol is not simply a substance chosen from a list of steroids, but a compound that has the mechanism of action of a soft steroid. These advantages are mentioned in the present specification on pages 2-3. Thus, the combination of loteprednol/DFHO not only provides synergistic anti-inflammatory effects, but at the same time reduced side effects compared to classical steroids.

For all of the above reasons, it is respectfully submitted that the presently pending claims are not obvious from Barsig in view of Hellberg et al. Reconsideration and withdrawal of the rejection are respectfully requested.

All objections and rejections having been addressed, it is respectfully submitted that the application is in condition for allowance, and Notice to that effect is respectfully requested.

Respectfully submitted,

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Ann S. Hobbs, Ph.D.
Registration No. 36,830
VENABLE LLP
P.O. Box 34385
Washington, D.C. 20043-9998
Telephone: (202) 344-4000
Telefax: (202) 344-8300

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